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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/824,941

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EXAMINER

MALLARI, PATRICIA C

ART UNIT

PAPER NUMBER

3735

MAIL DATE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/824,941	<b>Applicant(s)</b> LEE ET AL.	
	<b>Examiner</b> PATRICIA C. MALLARI	<b>Art Unit</b> 3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 02 February 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 38-48, 50-72, 75-81, and 83-86 is/are pending in the application.
- 4a) Of the above claim(s) 43 and 45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 38-42, 44, 46-48, 50-72, 75-81 and 83-86 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/14/09</u> .  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

This is a final Office action. Any new grounds of rejection were necessitated by the applicants' amendments to the claims.

### ***Election/Restrictions***

Applicant's election without traverse of Group II, Species A1, B1, and C1 in the reply filed on 2/2/08 is acknowledged. Claims 43 and 45 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 38-42,44,46-48, 50-72, 75-81, and 83-86 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 38 recites, "one or more characteristics" on line 3 of the claim, "a first respiration characteristic" on lines 11-12 of the claim, and "a second respiration characteristic" on line 12 of the claim. It is unclear whether the first and second respiration characteristics recited on lines 11-12 of the claim are the same as or different from the one or more characteristics recited on line 3 of the claim. Applicants should clarify.

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Claim 81 recites, “one or more characteristics” on line 3 of the claim, “a first respiration characteristic” on line 8 of the claim, and “a second respiration characteristic” on line 9 of the claim. It is unclear whether the first and second respiration characteristics recited on lines 8 and 9, respectively, are the same as or different from the one or more characteristics recited on line 3 of the claim. Applicants should clarify.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 38-40, 46, 47, 50-53, 64, 71, 72, 75-77, 79, 81, 82, and 85 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 5860918 to Schrudi et al. Regarding claims 38 and 81, Schrudi teaches a system for characterizing respiration of a patient comprising a respiration waveform sensor 102, 106 configured to acquire a respiration waveform (see entire document, especially col. 5, lines 26-32 of Schrudi), wherein apnea and desaturation waveforms are respiration waveforms. A respiration processor is configured to determine at least one characteristic associated with the respiration and comprising a trigger circuit configured to detect a triggering event (see entire document, especially col. 5, lines 39-49; col. 6, lines 7-35 of Schrudi). A waveform generator is coupled to the respiration waveform sensor and processor and is

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configured to generate a marked respiration waveform comprising the respiration waveform 214, 216 and symbols indicating at least one characteristic associated with the respiration, the generation of the marked respiration waveform being activated in response to the detection of the triggering event, wherein the marked waveform cannot be generated until an event occurs, since the marked waveform includes symbols indicating events (see entire document, especially fig. 2; col. 5, lines 39-49 of Schradi) . The symbols 210 include a first symbol indicating a first respiration characteristic and a second symbol indicating a second respiration characteristic different from the first, wherein the first and second symbols are aligned relative to the respiration waveform to indicate times of occurrence of the first and second respiration characteristics respectively (see entire document, especially col. 7, lines 4-34 of Schradi).

As to claims 38, 39, and 40, the applicants should note that the language “implantable” is merely intended use language which cannot be relied upon to define over the prior art of record, since Schradi teaches all of the claimed structural components and their recited relationships. The sensor, processor, and waveform generator of Schradi are each certainly capable of being implanted (i.e. of a shape and size allowing implantation) into something, or placed within something, such as the ground. Further, a component of any of the sensor, processor, and waveform generator is also certainly capable (i.e. of a shape and size allowing) of implantation into a body.

Regarding claim 46, a sensing system 102, 104, 106 is coupled to the processor and configured to sense at least one condition associated with respiration (see entire document, especially col. 5, lines 27-43 of Schradi).

Regarding claim 47, the sensing system comprises a physiological sensor (see entire document, especially col. 5, lines 27-32 of Schradi).

Regarding claim 50, the respiration processor comprises a disordered breathing processor configured to detect disordered breathing and the triggering event comprises the detection of the disordered breathing (see entire document, especially col. 5, line 66-col. 6, line 23 of Schradi).

Regarding claim 51, the disordered breathing processor is configured to determine at least one characteristic associated with the disordered breathing (see entire document, especially col. 5, line 66-col. 6, line 23 of Schradi).

Regarding claim 52, the at least one characteristic associated with the respiration comprises oxygen desaturation (see entire document, especially col. 6, lines 19-22 of Schradi).

Regarding claim 53, the at least one characteristic associated with the respiration comprises at least one characteristic of a pulmonary disease (see entire document, especially col. 6, lines 13-35 of Schradi).

Regarding claim 64, the at least one characteristic associated with the respiration comprises a duration of disordered breathing (see entire document, especially col. 7, lines 15-19 of Schradi).

Regarding claims 71 and 72, the respiration processor is configured to detect the at least one characteristic associated with the respiration based on physiological conditions and/or contextual conditions (see entire document, especially col. 6, lines 13-22; col. 7, lines 4-19 of Schradi).

Regarding claims 75-77 and 83, the waveform generator is configured to acquire at least one additional physiological waveform (see entire document, especially col. 5, lines 26-58 of Schradi), wherein the additional waveform may be a cardiac waveform (bradycardia).

Regarding claims 79 and 85, a display is configured to display the marked respiration waveform (see entire document, especially figs. 1, 2; col. 5, lines 40-43 of Schradi).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 41 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schradi, as applied to claims 38-40, 46, 47, 50-53, 64, 71, 72, 75-77, 79, and 81 above, and further in view of Us Patent No. 6,126,608 to Kemme et al. Schradi teaches the sensor, processor, and generator being coupled to an external device 120, but is silent as to the

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nature of such connection. However, Kemme teaches that a connection to a keyboard or other peripheral device may be done wirelessly (see entire document, especially the abstract; col. 2, lines 8-11 of Kemme). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the connection of Kemme to connect to the input or external device of Schradi, since Schradi teaches the external device being a keyboard, and Kemme teaches a wireless connection as being an appropriate connection to a keyboard.

Claim 42 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schradi, as applied to claims 38-40, 46, 47, 50-53, 64, 71, 72, 75-77, 79, and 81 above, and further in view of US Patent Application Publication No. 2004/0210261 to King et al. Schradi lacks any component being connected to a cardiac rhythm management device. However, King teaches a device wherein apnea and respiration characteristics may be monitored, wherein the sensor and processor are mechanically coupled to a cardiac rhythm management device (see entire document, especially figs. 1 and 2; paragraphs 6, 12, 34 of King). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to combine King with Schradi in order to effectively treat the patient's apnea.

Claims 44 and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schradi, as applied to claims 38-40, 46, 47, 50-53, 64, 71, 72, 75-77, 79, and 81 above, and further in view of US Patent Application Publication No. 2004/0210261 to



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King et al. Schradi lacks details as to the sensors, but states that one may be an apnea sensor. King teaches using an impedance sensor to obtain respiration information in order to detect apnea (see entire document, especially paragraph 34 of King).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the sensor of King as that of Schradi, since Schradi teaches using an apnea sensor, and King describes an appropriate such apnea sensor.

### ***Response to Arguments***

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

While new grounds of rejection have been made, the applicants have provided remarks regarding the Schradi reference, wherein the new grounds of rejection still rely on Schradi. In particular, the applicants argue that Schradi fails to teach generating a marked respiration waveform in which one symbol indicating a respiration characteristic is aligned relative to the respiration waveform to indicate a time of occurrence.

However, Schradi clearly teaches generating a marked waveform as shown in figure 2 of the reference, wherein, for example, the desaturation % or apnea duration is a respiration waveform, and symbols 210 are aligned with the waveform to mark the occurrence of different events or respiration characteristics, such a desaturation, bradycardia, or an apnea event.

As to the applicants' arguments regarding Schradi's event trigger, the applicants should further note that claim 38 fails to relate the triggering event and generating the

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marked waveform. Moreover, the occurrence of an event clearly triggers the display of a marked waveform in that the event markings are not generated on the display until an event occurs and the marked waveform is a waveform having event markings displayed therewith.

### ***Allowable Subject Matter***

In light of the rejection under 35 U.S.C. 112, 2<sup>nd</sup> paragraph, no statement of allowability is being given at this time, although no prior art rejection has been made to claims 54-63, 66-70, 78, 80, and 84. Upon resolution of these issues, the prior art will be revisited.

However, regarding claim 48, the prior art of record fails to teach or fairly suggest the sensing system comprising a non-physiological sensor, in combination with all of the other limitations of the claims.

Regarding claims 54-63, the prior art of record fails to teach or fairly suggest the respiration processor being further configured to distinguish between different types of disordered breathing and the first respiration characteristics comprises a type of disordered breathing selected from the different types of disordered breathing, in combination with all of the other limitations of the claims.

Regarding claims 66-69, the prior art of record fails to teach or fairly suggest the characteristic associated with respiration comprising a respiration volume, minute ventilation, expiration slope, or expiration volume, in combination with all of the other limitations of the claims.

Regarding claim 70, the prior art of record fails to teach or fairly suggest the respiration processor being configured to detect the characteristic(s) associated with respiration based on morphological features of the respiratory waveform, in combination with all of the other limitations of the claims.

Regarding claims 78, 80, and 84, the prior art of record fails to teach or fairly suggest a communication device configured to transmit information about, a means for transmitting information about, or a memory configured to store information about at least one of the waveform, the one or more characteristics associated with the respiration, and the marked respiration waveform, in combination with all of the other limitations of the claims.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PATRICIA C. MALLARI whose telephone number is (571)272-4729. The examiner can normally be reached on Monday-Friday 10:00 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Patricia C. Mallari/  
Primary Examiner, Art Unit 3735

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